UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CAMILLE GOMEZ, MIRIAM GREEN,
ILUMINADO MARRERO, JACQUELYN PACKER,
LYDIA PEREZ, HILDA POPE,
ANABERTA RAJWA, ANNA RUSSO
SARAMMA ABRAHAM, MARTIN ACKERMAN
EDOM ADOM, RICHARD ALGARIN,
ANTHONY ARTURI, EUGENE ANDRYSHAK,
KENNETH BALBAN, MICHAEL BARON,
FRANKLYN BISHOPP, GEORGE BARDEN
MARIE BOUZI, REGINA CARROLL,
EDITH GILLESPIE, ETHEL GISIANO
KATHLEEN HAHNENBERGER,
ROBERT HAINES, FRANCES HEALY,
ANNA KONOPKA, JAMES LAGARDE,
ROBERT LEE, PAUL MARCUS
MARSHA McCREADIE, ROSE MEDINA,
ANTHONY MERCURIO, DOROTHY NELSEN,
WILLIAM PEKROL, EDWARD ROACH,
SAMUEL ROSA, JULIANNA SCHWARTZ,
ELOVISTINE SMITH, JOHN SMITH,
ANN SOLLECITO, PAUL SUR,
MARTHA THROWER, EVERSLEY VAUGHAN,
SENORIA VEGA, ANNIE LEE WARREN,
ELMER WRIGHT and JOSEPH WRIGHT,
Individually, et al, on behalf of themselves and all
others similarly situated, including their lawfully
married spouses and "John Does" 1 to 1000,
individually and as representatives, either Administrator,
Administratrix, Executor or Executrix of the Estates of
unknown Vioxx users who died as a result of use of
Vioxx and the surviving spouses, on behalf of themselves
and others similarly situated,

Plaintiffs,

-against-

MERCK & CO., INC.,

Defendant.

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Docket No.: Civ. 06-0545

CLASS ACTION
COMPLAINT AND JURY DEMAND

CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiffs, by their attorneys the LAW OFFICES OF WEINER CARROLL & STRAUSS, as and for their Complaint per F.R.C.P. 15(a), herein allege:

1. This case involves the prescription drug VIOXX ("Vioxx") generic name rofecoxib, which was researched, designed, developed, manufactured, marketed, promoted, advertised and distributed by defendant Merck & Co, Inc. ("Merck") for relief of pain and inflamation (swelling and soreness) in adults suffering from osteoarthritis, rheumatoid arthritis, short-term pain, menstrual pain, and migraine headaches; and in juveniles suffering from rheumatoid arthritis.

2. At all times relevant to this litigation, defendant Merck misrepresented the safety of Vioxx, a defective product, and negligently manufactured, marketed, advertised, promoted and

sold Vioxx as a safe prescription medication, when in fact defendant Merck knew or should have known that Vioxx was not safe for its intended purpose for patients for whom it was prescribed and to whom it was sold; and that Vioxx caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

3. In public statements to the press, Merck has estimated that l05 million US prescriptions for Vioxx were written between May, l999 and August, 2004. Based on this estimate, Merck has estimated that approximately 20 million patients have taken Vioxx in the US since the launch of the drug in May of l999.

4. Pursuant to 23(b)(3) of the Federal Rules of Civil Procedure, plaintiffs seek certification of a National class in this matter, consisting of:

> All persons residing in the United States who took Vioxx in any dose at any time between May 20, l999, when Vioxx was first approved by the United States Food and Drug Administration ("FDA") and September 30, 2004,

> when Vioxx was withdrawn from the market, and who claim personal injuries or assert wrongful death claims arising from ingestion of Vioxx.

5. Alternatively, in the event that this Court determines that a national personal injury class would not satisfy the requisites for class certification pursuant to Rule 23 of the Federal Rules of Civil Procedure, plaintiffs would move for the certification of individual state class actions, consisting of, as to each state for which certification is sought:

> All residents of [state] who took Vioxx in any dose at any time between May 20, l999, when Vioxx was first approved by the United States Food and Drug Administration ("FDA") and September 30, 2004, when Vioxx was withdrawn from the market, and who claim personal injuries or assert wrongful death claims arising from ingestion of Vioxx.

6. In the event that plaintiffs pursue the course of action set forth in paragraph 6, supra, plaintiffs intend to request that this MDL Court file a suggestion of remand to sever the question of class certification and/or to remand to the transferor forum each state class action as to which plaintiffs seek certification, solely for purposes of addressing the class certification question. Remand of the class certification question will allow appellate review of the state class certification question by the appropriate Circuit Court(s), thus ensuring that no party is prejudiced by the random selection of a transferee forum whose procedural jurisprudence would determine the class certification issue differently from the transferor forum. However, for purposes of uniformity and judicial efficiency, plaintiffs would further request that this Judicial Panel suggest to the Chief Judge of each transferor court to appoint this Court to sit by ad hoc designation over the class certification issue of each transferor court as to which such remand has

been sought. Plaintiffs submit that these adjudications may be conducted by this Court while remaining in the vicinage of the Eastern District of Louisiana.

II. STATEMENT OF JURISDICTION

7. Federal jurisdiction is proper under 28 U.S.C. l332 as the amount in controversy exceeds $75,000 and all of the plaintiffs are of diverse citizenship with the defendant.

8. As to plaintiffs, federal jurisdiction is proper under the Class Action Fairness Act, 28 U.S.C. 1332(d) as the amount in controversy exceeds $75,000.00 and diversity of citizenship exists between a class of plaintiffs and the primary defendant.

9. The jurisdiction of this Court over the claims asserted herein is founded upon 28 U.S.C. 1332, in that the action is one between citizens of a state or states and citizen of a foreign state, and the matter in controversy, exclusive of interest and costs, exceeds the sum of $100,000.

III. IDENTITY OF PARTIES

10. **NEW YORK**: Plaintiffs, citizens of the State of New York, bring this action on behalf of themselves and all others similarly situated in the State of New York.

11. That at all times hereinafter mentioned, Plaintiff, **CAMILLE GOMEZ**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

12. That at all times hereinafter mentioned, Plaintiff, **MIRIAM GREEN**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

13. That at all times hereinafter mentioned, Plaintiff, **ILUMINADO MARRERO**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

14. That at all times hereinafter mentioned, Plaintiff, **JACQUELYN PACKER**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

15. That at all times hereinafter mentioned, Plaintiff, **LYDIA PEREZ**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

16. That at all times hereinafter mentioned, Plaintiff, **HILDA POPE**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

17. That at all times hereinafter mentioned, Plaintiff, **ANABERTA RAJWA**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

18. That at all times hereinafter mentioned, Plaintiff, **ANNA RUSSO**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

19. That at all times hereinafter mentioned, Plaintiff, **SARAMMA ABRAHAM**, was and still is a resident of the State of New York, residing in Rockland County, State of New York.

20. That at all times hereinafter mentioned, Plaintiff, **MARTIN ACKERMAN**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

21. That at all times hereinafter mentioned, Plaintiff, **EDOM ADAM**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

22. That at all times hereinafter mentioned, Plaintiff, **RICHARD ALGARIN**, was and still is a resident of the State of New York, residing in Orange County, State of New York..

23. That at all times hereinafter mentioned, Plaintiff, **ANTHONY ARTURI**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

24. That at all times hereinafter mentioned, Plaintiff, **EUGENE ANDRYSHAK**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

25. That at all times hereinafter mentioned, Plaintiff, **KENNETH BALBAN**, was and still is a resident of the State of New York, residing in Rockland County, State of New York.

26. That at all times hereinafter mentioned, Plaintiff, **MICHAEL BARON**, was and still is a resident of the State of New York, residing in Putnam County, State of New York.

27. That at all times hereinafter mentioned, Plaintiff, **GEORGE BARDEN**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

28. That at all times hereinafter mentioned, Plaintiff, **FRANKLYN BISHOPP**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

29. That at all times hereinafter mentioned, Plaintiff, **MARIE BOUZI**, was and still is a resident of the State of New York, residing in New York County, State of New York.

30. That at all times hereinafter mentioned, Plaintiff**, REGINA CARROLL**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

31. That at all times hereinafter mentioned, Plaintiff, **EDITH GILLESPIE**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

32. That at all times hereinafter mentioned, Plaintiff, **ETHEL GISIANO**, was and still is a resident of the State of New York, residing in Ulster County, State of New York.

33. That at all times hereinafter mentioned, Plaintiff, **KATHLEEN HAHNENBEREGER**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

34. That at all times hereinafter mentioned, Plaintiff, **ROBERT HAINES**, was and still is a resident of the State of New York, residing in Ulster County, State of New York.

35. That at all times hereinafter mentioned, Plaintiff, **FRANCES HEALY**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

36. That at all times hereinafter mentioned, Plaintiff, **ANNA KONOPKA**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

37. That at all times hereinafter mentioned, Plaintiff, **JAMES LAGARDE**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

38. That at all times hereinafter mentioned, Plaintiff, **ROBERT LEE**, was and still is a resident of the State of New York, residing in Rockland County, State of New York.

39. That at all times hereinafter mentioned, Plaintiff, **PAUL MARCUS**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

40. That at all times hereinafter mentioned, Plaintiff, **MARSHA McCREADIE,** was and still is a resident of the State of New York, residing in New York County, State of New York.

41. That at all times hereinafter mentioned, Plaintiff, **ROSE MEDINA**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

42. That at all times hereinafter mentioned, Plaintiff, **ANTHONY MERCURIO**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

43. That at all times hereinafter mentioned, Plaintiff, **DOROTHY NELSEN**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

44. That at all times hereinafter mentioned, Plaintiff, **WILLIAM PEKROL**, was and still is a resident of the State of New York, residing in Rockland County, State of New York 45. That at all times hereinafter mentioned, Plaintiff, **EDWARD ROACH**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

46. That at all times hereinafter mentioned, Plaintiff, **SAMUEL ROSA**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

47. That at all times hereinafter mentioned, Plaintiff, **JULIANNA SCHWARTZ**, was and still is a resident of the State of New York, residing in Bronx County, State of New York.

48. That at all times hereinafter mentioned, Plaintiff, **JOHN SMITH**, was and still is a resident of the State of New York, residing in Orange, County, State of New York.

49. That at all times hereinafter mentioned, Plaintiff, **ELOVISTINE SMITH**, was and still is a resident of the State of New York, residing in Orange County, State of New York.

50. That at all times hereinafter mentioned, Plaintiff, **ANN SOLLECITO,** was and still is a resident of the State of New York, residing in Westchester County, State of New York.

51. That at all times hereinafter mentioned, Plaintiff, **PAUL SUR**, was and still is a resident of the State of New York.

51a. That at all times hereinafter mentioned, Plaintiff, **MARTHA THROWER,** was and still is a resident of the State of New York, residing in Dutchess County, State of New York.

5b. That at all times hereinafter mentioned, Plaintiff, **EVERSLEY VAUGHAN**, was and still is a resident of the State of New York, residing in New York County, State of New York.

52. That at all times hereinafter mentioned, Plaintiff, **SENORIA VEGA**, was and still is a resident of the State of New York, residing in New York County, State of New York.

53. That at all times hereinafter mentioned, Plaintiff, **ANNIE LEE WARREN**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

54. That at all times hereinafter mentioned, Plaintiff, **ELMER WRIGHT**, was and still is a resident of the State of New York, residing in New York County, State of New York.

55. That at all times hereinafter mentioned, Plaintiff, **JOSEPH WRIGHT**, was and still is a resident of the State of New York, residing in Westchester County, State of New York.

DEFENDANT

56. Through information and belief, the Defendant, **MERCK & CO., INC**., is a corporation duly formed according to the law of the State of New Jersey, with a principal offices located at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey.

57. The Defendant, **MERCK & CO., INC**., transacted business in the State of New York and elsewhere in the United States, its territories and possessions, and throughout the world, selling pharmaceutical products at all times hereinafter mentioned.

58. Through information and belief, the Defendant, **MERCK & CO., INC**., supplied pharmaceutical drugs to the Plaintiff in the State of New York and elsewhere in the United States at all times hereinafter mentioned.

59. Through information and belief, the Defendant, **MERCK & CO., INC**., solicited and engaged in a persistent course of business in the State of New York and elsewhere in the United States at all times hereinafter mentioned.

60. Through information and belief, the Defendant, **MERCK & CO., INC**., derives substantial revenue from goods sold and used in the State of New York and elsewhere in the United States at all times hereinafter mentioned. In addition, **MERCK & CO., INC**., in the relevant years engaged in direct advertising through the media for the sale of its product, Vioxx, which advertising was both seen and read by the aforementioned Plaintiffs, who relied upon the advertisements in requesting and ultimately purchasing or using this product.

61. At all times pertinent hereto, **Merck** developed, designed, researched, manufactured, promoted, marketed, advertised, distributed, and sold Vioxx from its New Jersey headquarters and New Jersey research and development facilities, for use in human individual patients such as plaintiffs identified herein, and those whom they seek to represent throughout the United States.

IV. FACTUAL ALLEGATIONS COMMON TO ALL CLASS MEMBERS

A. Vioxx is a Non-Steroidal Anti-Inflammatory Drug ("NSAID") that Selectively Blocks Production of Cyclooxygenase-2 (COX-2").

62. Vioxx belongs to a class of drugs known as non-steroidal anti-inflammatory drugs or "NSAIDs" which are used to reduce pain. NSAIDs generally reduce pain by blocking the production of an enzyme called prostaglandin G/H synthase, which consists of two similar forms cyhclooxygenase-1 ("Cox-l") and Cyclooxygenase-2 ("Cox-

2"). Vioxx is a selective inhibitor of Cox-2. Vioxx reduces pain by selectively blocking the production of "Cox-2."

63. Other, older NSAIDs, which inhibit production of Cox-l as well as Cox-2 also provide effective relief from pain and inflammation. Because Cox-l can adversely affect the gastro-intestinal ("GI") tract, traditional NSAIDs have been associated with potential GI toxicity.

64. In the late l980's and early l990's Merck was facing a business crisis, because patents on several of its best selling drugs, including Vasotec, Prinivil, Mevacor, Pepcid, and Prilosec were expiring. Never had a pharmaceutical company faced the loss of so many million dollar patents at the same time. Merck management even feared that Merck might not survive as a company.

65. In or about the summer of l992, Merck began a Cox-2 research program at the Merck Frosst Centre for Therapeudic Research in Quebec, Canada. Merck scientists explored the hypothesis that the therapeudic utilities of NSAIDs were due to the inhibition of Cox-l.

66. At the time, Merck management realized that the development of an NSAID that operated by selectively blocking Cox-2 could produce a much needed "Blockbuster" for the company. As the company has acknowledged, the race was on to find a selective inhibitor of Cox-2.

67. During l992, Merck became aware that both Dupont and Taisho, a Japanese pharmaceutical company, had selective Cox-2 inhibitors in development. Almost every one of the more than three hundred scientists and support staff at the Merck-Frosst Centre for Therapeudic Research worked on the discovery and development of Vioxx.

After discarding one compound because it lacked sufficient selectivity for Cox-2, and another because metabolic studies raised questions of possible drug-drug interactions, Merck continued to research and develop the compound that eventually became known as Vioxx.

68. On or about December 20, l994, Merck filed its first investigational new drug (IND) application with the FDA to conduct clinical trials of Vioxx in humans. The intended use of the drug identified in the IND was the treatment of osteoarthritis and acute pain.

69. Following FDA approval of Vioxx in May of l999, Merck marketed Vioxx as a selective Cox-2 inhibitor, which unlike traditional NSAIDs, did not inhibit the production of Cox-l. Merck claimed that since Vioxx was the most selective inhibitor of Cox-2 on the market, it conferred the anti-inflammatory and analgesic benefits of traditional NSAIDs without the associated gastrointestinal toxicity. Accordingly, Merck asserted that Vioxx was the safest NSAID on the market.

70. For the more than five years that Merck marketed Vioxx in the United States, it remained Merck's leading drug for control of acute pain and chronic pain associated with osteoarthritis, rheumatoid arthritis, migraine headaches, and dysmenorrheal pain.

71. In 2003 alone, worldwide sales of Vioxx reached 2.5 billion dollars (U.S.), following the most impressive global sales growth of any drug in history. From a marketing standpoint, Vioxx was an unqualified, if not unprecedented, success. However, from a public safety standpoint, it was an unmitigated disaster. Vioxx's pre- and post-marketing history was plagued with safety concerns which Merck repeatedly ignored, concealed and/or downplayed.

72. The astonishing marketing success of Vioxx became so central to Merck's financial well-being, that Edward Scolnick, former President of Merck Research Laboratories in Rahway, New Jersey, stated that had the drug failed, Merck would have been a very different company.

73. Despite the efforts of numerous healthcare professionals, Merck successfully downplayed, and in some instances, actively concealed, the fact that Vioxx significantly increased the risk of adverse thrombotic events, including devastating cardiovascular and cerebrovascular injuries such as myocardial infarctions (heart attacks) and strokes, until the drug was finally recalled in late September 2004.

74. Because Vioxx inhibited Cox-2 without substantially inhibiting Cox-l, it among other things, created a homeostatic imbalance that could result in increased aggregation of blood platelets or blood clotting and thereby substantially increased the risk of adverse cardiovascular and cerebrovascular adverse events, including heart attacks - both clinically recognized and unrecognized - ischemic strokes, and other serious injuries. Merck had reason to know and did know of these serious adverse events in patients who ingested Vioxx.

B. Merck Knew of Vioxx's Cardiotoxic and Pro-thrombotic Effects before it was Approved and Marketed.

1. Merck's Knowledge of the Risks Associated with Vioxx Dates to at Least November l996.

75. Merck sought to market Vioxx as an alternative to earlier NSAIDs such as aspirin, which had frequently been associated with adverse gastrointestinal side effects. As early as November, l996, years before FDA approval of Vioxx in May, l999, Merck recognized that unless taken in conjunction with aspirin, Vioxx posed a "substantial risk"

of “significantly higher rates” of cardiovascular adverse events such as myocardial infarctions, strokes and transient ischemic attacks because, as a selective Cox-2 inhibitor, it lacked aspirin’s “anti-platelet [i.e., anti-clotting] effect.”

76. In fact, early in the development program for Vioxx, to demonstrate that it selectively inhibited Cox-2, Merck used a platelet aggregation assay to assess the drug’s effect on Cox-l. That research established that Vioxx did not affect thromboxane production or platelet aggregation because it did not inhibit Cox-l. In addition, a Merck-sponsored study found that Vioxx, unlike several other NSAIDs against which it was tested, had no appreciable anti-platelet effect (Protocol 06l).

77. Two months later, in February l997, Vioxx researcher Briggs Morrison conceded that “without Cox-l inhibition you will get more thrombotic events and kill drug”.

78. Responding to this observation, Merck’s Vice President of Clinical Research Alise Reicin, complained:

> This is a no win situation. The relative risk of [adverse GI events with] even low dose aspirin is 2-4 fold. Yet the possibility of increased CV [cardiovascular] events of great concern (I just can’t wait to be the one to present those results to senior management!). What about the idea of excluding high risk CV patients - i.e. those that have already had an MI, CABG, PTCA? This may decrease the CV event rate so that the difference between the two groups would not be evident. The only problem would be - would we be able to recruit any patients?

79. By early l998, Merck’s own clinical investigators, in fact, based on findings from a Merck-sponsored study (Protocol 023) advised the company that by inhibiting Cox-2, Vioxx, at the cellular level of blood vessel linings, may alter the homeostatic balance between prostacyclin - a Cox-2 platelet inhibitor that dilates blood vessels - and

thromboxane - a Cox-l platelet activator that constricts blood vessels - such that it could provoke the creation of blood clots.

80. In December l997, Merck appointed a “Task Force” to investigate the incidence of cardiovascular serious adverse events in the ongoing Vioxx clinical trials. The reason for the investigation was the unexpected result of an early clinical trial which showed a decline in the levels of PGI-2, the most potent of all inhibitors of platelet aggregation, but no inhibition of systemic thromboxane, in the urinalysis of patients on Vioxx. This imbalance triggered a concern over the potential for thrombotic events.

81. The task force agreed to investigate the incidence of thrombotic events by analyzing the ongoing osteoarthritis (OA) trials. Because the trials were still blinded as to treatment groups, it could not be determined whether the adverse events in the database had occurred in the Vioxx, placebo or compared to drug populations. Therefore, the Task Force designed a study in which cardiovascular events from all arms of the OA trials would be added together, and the combined groups’ incidence rate would be compared to placebo patients from trials of other Merck drugs. An expedited time frame was established for completion of the analysis, because of the rush to get Vioxx to market ahead of competitors.

82. In January, l998, the analysis pursuant to the Task Force plan showed a statistically significant increased relative risk of 2.l6 for females in the Vioxx study versus the placebo group selected by Merck for comparison. These results constituted a clear signal of cardiovascular toxicity that should have triggered immediate investigation and concern. Instead, Merck made an after-the-fact claim that the placebo comparison group must have had an “atypically low” incidence of cardiovascular events,

such that the higher rate in the Vioxx group was downplayed. Further, Merck changed the rules after the game had been played, by deciding to compare the rate in the Vioxx group to a so-called "background" rate, even though no such comparison was stated in the plan for the study. Merck intentionally chose an inappropriate "background" rate for comparison, from a published study of older patients at high risk of cardiovascular disease. Based upon the result of this comparison, Merck incorrectly dismissed the signal as of no concern. Merck failed to disclose the results of this pre-marketing analysis, and instead had misrepresented that it had no indication of cardiovascular risk before Vioxx was marketed.

83. In or about l998, six months before Merck filed its New Drug Application ("NDA") with the FDA, Merck's Scientific Advisory Board for the drug recommended that researchers "systematically collect data on cardiovascular (CV) events in all clinical trials" for Vioxx.

84. In issuing this recommendation, the Board noted that some of its consultants were concerned that "[b]ased on the data on PGI [prostaglandin] metabolism obtained for Vioxx, it is conceivable that Vioxx could disturb the [endothelium-platelet] interaction to favor platelet aggregation."

85. On or about November 23, l998, Merck submitted a New Drug Application ("NDA") for Vioxx l2.5 mg and 25 mg tablets to treat the signs and symptoms of osteoarthritis, the management of acute pain and the treatment of primary dysmenorrhea.

86. On or about May 20, l999, the FDA approved Vioxx for the relief of signs and symptoms of acute pain, dysmenorrhea, and osteoarthritis, a chronic swelling and painful joint disease of one or more joints.

C. The Vigor Study showed significant increases in Cardiovascular events occurring in patients taking Vioxx as opposed to Naproxen.

87. Signs of Vioxx's risks of serious adverse events emerged soon after the FDA's approval of the drug.

88. On or about January 6, l999, a Merck-sponsored 8,000 patient clinical study known as the VIOXX Gastrointestinal Outcome Research Study (the "VIGOR study") was begun in rheumatoid arthritis patients comparing VIOXX with the over-the-counter NSAID Naproxen to obtain information regarding clinically meaningful gastrointestinal events, and purportedly to develop a large controlled data-base for overall safety assessment.

89. Merck excluded "high" cardiovascular risk patients from the VIGOR trial.

90. On or about November l8, l999, Merck's senior biostatistician, Deborah Shapiro, provided a tightly controlled, highly confidential interim safety report to the VIGOR study's Data Safety and Monitoring Board ("DSMB"), which showed that almost twice as many serious cardiovascular events were occurring among patients taking Vioxx as among those taking Naproxen.

91. In or about March of 2000, Merck released the results of the VIGOR study. The study data revealed, among other things, that Vioxx users suffered five times as many heart attacks than their Naproxen counterparts. In addition, serious cardiovascular events (including heart attacks, ischemic strokes, unstable angina, and

sudden unexplained deaths) were reported for more than twice as many Vioxx as Naproxen patients.

92. Despite the results of the VIGOR study Merck failed to include in its Vioxx label a cardiovascular warning that VIOXX was contraindicated in high risk CV patients.

93. Vioxx had exhibited significantly greater cardiovascular toxicity than Naproxen within the first six weeks of the VIGOR study.

94. On March 9, 2000, shortly after completion of the VIGOR study, Edward M. Scolnick, former president of Merck Research Laboratories, concluded that "the CV [cardiovascular] events are clearly there" and stated that Merck should be prepared to "make clear to the world" that Vioxx's cardiovascular toxicity "is a class effect" (i.e. and effect of the class of selective Cox-2 inhibitors) that is "mechanism based as we worried it was" and as some of the company's consultants had maintained.

95. Merck ignored the causal relationship between Vioxx and this significantly increased rate of cardiovascular events in the VIGOR study. Instead, Merck seized upon and widely and continuously disseminated the post hoc rationalization that the VIGOR study showed that Naproxen reduced cardiovascular risk (i.e., it exerted a "cardioprotective effects"), not that Vioxx posed a serious cardiovascular hazard, an explanation with scant scientific support. Indeed, both the scientific literature and Merck consultants had concluded that Naproxen lacked any such cardioprotective effect.

96. Merck continued to publish and describe that Naproxen had a cardioprotective effect, notwithstanding that Italian pharmacologist Carlo Patrono, one of Merck's own consultants and an expert in the platelet effects of cyclooxygenase-inhibiting drugs (whom Merck regarded as "the world's most respected and

knowledgeable“ scientist in his field) advised Merck in March 2000, that the dramatic cardiovascular effects observed in the VIGOR study could not be attributed plausibly to Naproxen for several reasons.

97. Furthermore, on or about March 24, 2000, University of Pennsylvania pharmacologist Garrett Fitzgerald, then acting as a Merck consultant, advised Merck of a paper in press that included Naproxen among several NSAIDs which, in contrast to aspirin, had no significant effect on the incidence of first nonfatal myocardial infarctions in females in an epidemiological study.

98. In or about January 2002, a study by Wayne A. Ray, et al. Was published in The Lancet that disproved Merck’s Naproxen theory, concluding that Naproxen and other NSAIDs had not been shown to protect against the risk of coronary heart disease.

99. After the VIGOR study, evidence of the dangers of cardiovascular and cerebrovascular adverse events associated with Vioxx use continued to surface.

100. In June of 2000, industry-sponsored studies presented at the European United League Against Rheumatism (“EULAR”), an organization in which Merck is a member and a corporate sponsor, showed that Vioxx use resulted in statistically significant increases in hypertension and myocardial infarctions.

101. Merck knowingly downplayed and, in certain instances, withheld from publication, the severity of cardiovascular and cerebrovascular risks associated with Vioxx. For example, Merck downplayed this information in connection with the New England Journal of Medicine’s November 2000 reporting regarding the VIGOR study, authored by Merck sponsored authors.

102. On or about May 22, 200l,. Merck issued a press release through PR Newswire touting and "reconfirm[ing] the favorable cardiovascular safety profile of Voxx".

103. In a warning letter it issued four months later, the FDA, severely rebuking Merck, advised that:

> your claim in the [May 22, 200l] press release that Vioxx has a 'favorable cardiovascular safety profile', is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to Naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (l0l events, 2.5%) as in the Naproxen treatment group (46 events, l.l%) in the VIGOR study.

104. On or about August 22, 200l, the Journal of the American Medical Association ("JAMA") published an article authored by cardiologists from the Cleveland Clinic Foundation entitled "Risk of Cardiovascular Events Associated with Selective Cox 2 Inhibitors." The JAMA article reported the Cleveland Clinic's evaluation of two randomized trials of more than l5,000 patients, comparing Pfizer's Celebrex in a study called CLASS and the VIGOR study involving Vioxx to placebo. The Cleveland Clinic reported that "the annualized myocardial infarction rates for COX 2 inhibitors in both VIGOR and CLASS were significantly higher than that in the placebo group "One day before, and in anticipation of publication of, the JAMA article, Merck issued a statement claiming: "We have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo."

105. On or about August 23, 200l, the day after the JAMA article was published, Merck stated in another press release: “The Company stands behind the overall and cardiovascular safety profile of VIOXX.”

106. In October 200l, Merck learned of the publication of an article stating that there was a higher reporting rate for Vioxx compared to Celebrex, for adverse events relating to renal and cardiovascular effects. Merck responded by conducting an internal analysis of reported adverse events for Vioxx and Celebrex. Merck’s analysis showed a greater reporting rate of myocardial infarction, as well as congestive heart failure and related illnesses, for Vioxx in comparison to Celebrex. Merck disregarded this signal of cardiovascular toxicity and failed to disclose it to the public. Instead, Merck blamed the result on an alleged discrepancy in the number of events entered to the regulatory database for the two drugs. As in the case of the Task Force analysis of l997 and the VIGOR study of 2000, Merck once again searched for and found a reason to exonerate Vioxx and keep it on the market.

107. In or about 2002, the FDA approved an additional indication for the use of Vioxx for the relief of the signs and symptoms of rheumatoid arthritis in adults, which affects more than two million additional Americans.

108. Merck Pursued an Aggressive and Misleading Marketing Campaign in that Merck persistently failed to advise the medical community and patients of serious cardiovascular and cerebrovascular adverse events occasioned by the use of Vioxx.

109. Merck’s marketing strategy began in the l990s. Merck began to aggressively market and sell Vioxx by falsely misleading potential users such as the consumer plaintiffs and members of the Class about the product and by failing to protect

the consumers from serious dangers which the Defendant knew or should have known would result from the drug's use.

110. Defendant Merck wildly and successfully blitz-marketed Vioxx in the U.S. by undertaking an advertising campaign extolling the virtues of Vioxx in order to induce widespread use of Vioxx. This direct-to-consumer advertising campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and other health care providers and HMOs, and promotional material provided directly to potential Vioxx users themselves.

111. The advertising campaign as a whole sought to create the image, impression and belief that the use of Vioxx was safe, had fewer side-effects and adverse reactions than other pain relief medications and would not interfere with daily life, even though Merck knew that these representations were false. Furthermore, Merck had no reasonable grounds to believe that any of these representations were true.

112. Merck engaged in a huge direct-to-consumer marketing scheme and failed to address these serious side effects with consumers until after Vioxx was withdrawn from the market. According to reports in the public press, Merck spent an estimated $45 million advertising Vioxx for a mere eight months in 2004.

113. In the television advertising directed to consumers, Merck promoted Vioxx in the following widely-disseminated advertisement featuring a testimonial from former Olympic skater Dorothy Hammill:

> It seems like only yesterday. When I started skating at 8 years old - I never thought I'd experience the thrill of winning a medal. With all the great memories has come another thing I thought I'd never experience - the pain of osteoarthritis. Vioxx is here, a prescription medicine for osteoarthritis pain. With one little pill

> A day Vi oxx can provide po werful super 24 hour ... relief. Vioxx specifically targets only the COX 2 enzyme.
> A key source of arthritis pain. Super. See our ad in Prevention.
>
> People with allergic reactions such as asthma to aspirin - see our ad in Prevention - or other arthritis medicines should not take Vioxx
> In rare cases, serious stomach problems such as bleeding can occur without warning.
> Tell your doctor, if you have liver or kidney problems.
> For more information [superimpose] 1-888-36VIOXX talk to your doctor about once daily Vioxx for the relief of osteoarthritis pain.
>
> Perhaps my biggest victor is able to plan my day around my life - and not m pain.
>
> [superimpose] Your results may vary.
> Ask your doctor if Vioxx is right for you.
>
> Vioxx for every day victories.

114. Notably absent from this advertisement was any reference to the serious cardiovascular side effects manifested in Merck's clinical trials of Vioxx.

115. In print advertisements, Merck advertised Vioxx by picturing Dorothy Hammill accompanying the statement:

> Along with all the great memories has come something I thought I'd never experience - the pain of osteoarthritis.

The advertisements continued:

> VIOXX is here. 24 hour relief of the most common type of arthritis pain, osteoarthritis.
>
> It isn't about going for a medal. Or feeling like a kid again. It's about controlling the pain that can keep you from doing everyday things. And VIOXX may help. VIOXX is a prescription medicine for osteoarthritis, the most common type of arthritis.
> ONE PILL - ALL DAY AND ALL NIGHT RELIEF.
>
> You take VIOXX only once a day. Just one little pill can

> relieve your pain all day and all night for a full 24 hours ...
>
> VIOXX EFFECTIVELY REDUCED PAIN AND STIFFNESS.
>
> In clinical studies, one daily VIOXX effectively reduced pain and stiffness. So VIOXX can help make it easier for you to do the Things you want to do. By going for a morning glide on the ice. TAKE WITH OR WITHOUT FOOD.
>
> VIOXX doesn't' need to be taken with food. So you don't have to worry about scheduling VIOXX around meals.
>
> IMPORTANT INFORMATION ABOUT VIOXX.
>
> People with allergic reactions, such as asthma, to aspirin or other arthritis medicines should not take VIOXX. In rare cases, serious stomach problems, such as bleeding can occur without warning. Telly our doctor if you have liver or kidney problems, or are pregnant. Also, VIOXX should not be used by women in late pregnancy. VIOXX has Been extensively studied in large clinical trials. Commonly reported side effects include upper respiratory infection, diarrhea, nausea and high blood pressure. Report any unusual symptoms to your doctor. ASK YOUR DOCTOR OR HEALTHCARE PROFESSIONAL ABOUT VIOXX. CALL 1-800-9MERCKS FOR MORE INFORMATION, OR VISIT VIOXX.COM. PLEASE SEE IMPORTANT ADDITIONAL INFORMATION BELOW.

116. These direct-to-consumer advertisements make absolutely no mention of Vioxx's association with cardiovascular or cerebrovascular disease, notwithstanding that Merck had reason to know and, in fact, did know that Vioxx was causally related to serious cerebrovascular and cardiovascular adverse side effects.

117. At all times relevant, Vioxx had been promoted, marketed, and advertised by Merck directly to consumers and to medical care providers as a safe and effective pain reliever, similar to NSAIDs such as Advil (ibuprofen) and Aleve (Naproxen), but without any of the known side effects of other NSAIDs, most notably NSAID inducted GI

toxicity. Merck advertised, marketed and promoted Vioxx as a safe alternative that, unlike other NSAIDs did not damage the mucus membrane of the gut.

118. Medical care providers and consumers reasonably relied on Merck's misrepresentations to the effect that Vioxx was a safe alternative, easy to use, and perfect for long term use for "all day and all night relief" of pain. As a result, Merck sold millions of prescriptions of Vioxx in the United States.

119. Sales of Vioxx soared to $2.5 billion dollars in 2003 alone on the strength of the biggest direct-to-consumer marketing campaign ever undertaken by a pharmaceutical company for a prescription medication.

120. Merck purposefully and knowingly misrepresented, understated and otherwise downplayed the serious health hazards and risks associated with protracted Vioxx use - precisely the use for which Vioxx was most often prescribed and, in fact, was intended.

121. Merck, through the Vioxx promotional literature, audio conferences, professional meetings, press releases, and advertisements too numerous to catalogue herein, deceived plaintiffs, the members of the Class, potential consumers and the medical community by relating positive information, including testimonials from satisfied consumers; manipulating the statistics to suggest widespread acceptability and safety of the product; and intentionally understating the known adverse and serious health risks associated with the use of Vioxx. All of these promotional materials shared one common thread, the intentional misrepresentation of cardiovascular and cerebrovascular side effects known to Merck.

122. Merck concealed materially relevant information from potential Vioxx consumers and healthcare providers, and minimized user and prescriber concerns regarding the safety of Vioxx, while knowing that this materially relevant information was critical to the care of the consumers provided by healthcare providers.

123. Merck falsely misrepresented, inter alia:

(a) The severity, frequency and nature of adverse health effects caused by Vioxx;

(b) That adequate testing had been conducted concerning Vioxx; and

(c) That accurate information was reported about the adverse events.

D. The FDA Issued A Warning Letter on September l7, 200l, Indicating that Merck Had Engaged in "False or Misleading" Promotion of Vioxx.

124. On or about December l6, l999, less than seven months after it approved Vioxx, the FDA informed Merck by letter that it had engaged in "false or misleading"promotion of Vioxx. Specifically, the FDA concluded that Merck misrepresented (l) the drug's "safety profile" by claiming that it was "safer than a placebo" and (2) the drug's efficacy through "unsubstantiated" comparisons to the COX-2 inhibitor Celebrex and other NSAIDs.

125. Thereafter, Merck's conduct continued to be so egregious that the FDA issued a "Warning Letter" to Merck on or about September l7, 200l (hereinafter the "Warning Letter"), which demanded that Merck correct the false and misleading messages contained in the promotional campaign for Vioxx, the Vioxx press releases, and the oral representations made by Merck sales representatives to promote Vioxx.

126. The FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") reviewed the Vioxx promotional activities and materials and warned Merck that its market of Vioxx was: "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations."

127. Most, if not all, of the noted misrepresentations were made in reference to Merck's VIGOR study. According to DDMAC, Merck:

> engaged in a promotional campaign for VIOXX that minimizes the potentially serious cardiovascular findings that were observed in the VIOXX Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile of VIOXX. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on VIOXX were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID) Naprosyn (Naproxen).

128. The Warning Letter delineated the following misrepresentations made in six promotional audio conferences presented on behalf of Merck by Peter Holt, M.D., which were moderated by Merck employees; in Merckl press releases; and in oral representations made by Merck sales representatives to promote Voixx. According to this warning letter:

(a) Merck, its agents, employees and representatives minimized the rate of myocardial infarctions. For example, in a June 2l, 2000, audioconference, Merck began the discussion of the myocardial infarction rates observed in the VIGOR study by stating, "when you looked at the MI rate, the rate was different fo the two groups. The MI rate of VIOXX was 0.4 percent and if you looked at the Naproxen arm it was 0.l percent, so there was a reduction in the MI's in the Naproxen group." Merck offered what purported to be a scientific explanation, when, in fact, it was purely hypothetical. DDMAC wrote that, as Merck new, it was misleading to assert:

> that VIOXX does not increase the risk of [heart attacks] and that the Vigor finding is consistent with Naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you [Merck] fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that VIOXX may have pro-thrombotic properties.

(b) Merck knew that the promotional statement was false because the reason for the difference between the MI outcome for the Vioxx users versus the Naproxen users had not yet been determined.

(c) Merck carefully excluded from the promotional literature materially relevant information that Vioxx may have pro-thrombotic properties.

(d) DDMAC reprimanded Merck for understating the rate of myocardial infarctions. Merck had claimed that the MI rate was 0.2 percent for Naproxen and 0.l percent for Vioxx, which was completely inaccurate. DDMAC wrote:

> Contrary to [Merck's] claim that there was a higher rate of MIs in the Naproxen group compared to the VIOXX group, the MI rate for VIOXX in this subpopulation was l2 Mis among 3877 patients (0.3%) as compared to 4 Mis among 38787 patients (0.1%) for Naproxen.

(e) DDMAC reprimanded Merck for falsely claiming that the MI rate associated with the use of VIOXX was "basically the same as" the crude MI rate it the Celebrex study known as CLASS (Celebrex Long-Term Arthritis Safety Study);

(f) DDMAC reprimanded Merck for misrepresenting claims regarding the efficacy of Vioxx as compared to its competitor Celebrex. When publicly comparing the VIGOR study to the CLASS study, Merck failed to inform consumers that the patient populations in the two studies were extremely different. The VIGOR study excluded patients who had angina or congestive heart failure with symptoms that occurred at rest or with minimal activity as well as patients taking aspirin or other antiplatelet agents, all of which, if anything should have made Vioxx appear to present less cardiovascular toxicity. The CLASS study did not exclude these patients, therefore, making it more likely that the CLASS trial included patients with a higher risk for myocardial infarctions

prior to their ingestion of Celebrex. Nevertheless, Merck improperly compared two studies to misrepresent that Vioxx was more effective and safer than Celebrex;

(g) Merck failed to point out that the more affordable alternative, Naproxen, had been statistically proven to produce half as many myocardial infarctions as Vioxx. These misrepresentations and omissions were made not only at the promotional audio conference in June of 2000, but also at the annual meeting of the American Society of Health-Systems Pharmacists ("ASHP") in Los Angeles, California, on June 3 through June 6, 200l;

(h) DDMAC reprimanded Merck for making false statements about the risks of Vioxx therapy in patients who were taking warfarin. For example, at an audio conference on June l6, 2000, Merck stated:

> ...if you look at the thromboembolic agents, it's very clear that these selective COX 2 inhibitors [of which VIOXX is a member] have the benefit of not having platelet aggregation and bleeding time, and therefore, can be used safely in terms of post-op and with Coumadin.

This statement is directly contradicted by the precaution in the Product Insert, reprinted in the Physicians Desk Reference ("PDR"), which states: "... in post-marketing experience, bleeding events have been reported, predominantly in the elderly, in association with increases with prothrombin time in patients receiving VIOXX concurrently with warfarin".

(I) DDMAC rebuked Merck for its false and misleading marketing:

> Merck's promotional audio conferences and sales representative presentations failed to present the serous and significant risks associated with Vioxx use. They failed to state that Vioxx is contraindicated in patients who have experienced asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs.

129. In those marketing promotional presentations, Merck omitted the warning about the possibility of serious gastrointestinal toxicity occurring with use of Vioxx, such as gastric bleeding, ulceration or perforation; Merck failed to state that Vioxx's Product

Insert clearly defines certain precautions for use in patients with liver and kidney disease; failed to include information about patient populations in which Vioxx use is not recommended such as women in late pregnancy; and failed to include information about Vioxx's most common adverse events: serious cardiovascular and cerebrovascular events such as myocardial infarctions and ischemic strokes.

E. Adverse Events Continued to Occur Because of Vioxx Use and Merck Continued to Deny Vioxx's Dangers

130. According to the FDA Adverse Event Reporting System (ERS), through October, 2003, almost 2,000 adverse cardiovascular events were experienced by Vioxx users, including myocardial infarctions, cardiac arrest and cardiac failures.

131. On October 30, 2002, the Wall Street Journal reported that another study, sponsored by Merck, presented at the annual meeting of the American College of Rheumatology, confirmed an increased "risk of heart attacks I patients taking the pill [Vioxx]." According to the Wall Street Journal article, within the first 30 days of taking Vioxx, the risk of heart attack was increased 30% as compared to patients taking Celebrex.

132. In or about November 2003, Merck received preliminary results of a study it had commissioned performed by Merck personnel and Alex Walker, an executive at the Ingenix unit of United Health Group. The study revealed a statistically significantly greater incidence of myocardial infarction or unstable angina pectoris associated with use of Vioxx compared to the NSAIDs ibuprofen or diclofenac. The risk did not vary significantly by duration, use or dose. Merck never revealed the existence, much less the results of this study, prior to its withdrawal of Vioxx from the market in late September 2004.

133. In August 2004, Health Day News quoted the FDA as finding "this [the study referenced in the Wall Street Journal, supra 75] and other studies cast serious doubt on the safety" of Vioxx and that Celebrex "may be safer."

134. However, shortly after the August 24, 2004 FDA statement, Peter S. Kim, President of Merck Research Laboratories was quoted as saying that Merck "strongly disagrees" with the findings of this new study.

135. On August 26, 2004, the Street.com reported: "Merck Thursday released a detailed critique questioning the studies "significance."

F. Merck Finally Withdrew Vioxx from the Market in Response to Preliminary Results from its APPROVe study.

136. On or about November 8, l999, Merck submitted an IND application to the FDA to conduct clinical trials of Vioxx to pursue a claim that Vioxx was effective in preventing colon polyps and ultimately colon cancer.

137. Merck undertook another clinical study called the Adenomatous Polyp Prevention on Vioxx ("APPROVe") trial of Vioxx, 25 mg/day, to try to demonstrate the drug's effectiveness in preventing colon polyps.

138. At its first meeting in or about January 2002, the External Safety Monitoring Board ("ESMB") for the APPROVe trial voiced concerns regarding "trends noted in serious adverse clinical events and in thromboembolic events."

139. On or about September l7, 2004, the ESMB noted that "the trend for excess risk" for heart attacks and strokes " has continued to grow at each meeting over the last l-2 years." Consequently, the ESMB recommended that participating patients in

APPROVe be instructed to discontinue the study treatment. Merck abruptly discontinued the APPROVe study in mid-September 2004.

140. On or about September 27, 2004, Merck advised the FDA of the ESMB's recommendation. On or about September 28, 2004, Merck informed the FDA that it was withdrawing Vioxx from the market.

141. Merck has claimed since the release of the APPROVe results in September 2004 that the risk of heart attack and stroke did not appear until after subjects had taken V ioxx for more than l8 months, based on so-called "adjudicated" events. However, Merck has concealed from the public its internal analysis of "investigator reported" cardiovascular events, which showed that the Vioxx rate exceeded placebo throughout the entire period of the study.

142. Furthermore, Merck has concealed its internal analysis of such events showing a statistically significant increased risk for Vioxx versus placebo in the 0 to l8 month segment as well as the l9 to 36 month segment of the study. In a graph of the Kaplan-Meier cumulative rate curves" for Vioxx versus placebo, the Vioxx curve begins to exceed the placebo curve at approximately 2 to 3 months, and separates from the placebo incidence by an increasing margin for the remainder of the 36 month study. Merck's concealment of these data has been willful, intentional, and designed to minimize its potential liability to plaintiffs and the public.

143. The APPROVe study demonstrated that Vioxx doubled the risk of heart attack and stroke for consumers who had taken the drug for a period in excess of l8 months, as compared to subjects taking a placebo the same period of time.

144. In APPROVe, the relative risk for adverse cardiovascular events for Vioxx patients already at heightened cardiovascular risk was particularly high. For example, Vioxx patients with a history of symptomatic atherosclerotic cardiovascular disease were approximately 9-l/2

times more likely to suffer such events than their placebo counterparts, and those with a history of diabetes were approximately 6 times more likely to experience such events than patients in the placebo arm.

145. In March 2005, an article by Thal reported on exposure to Vioxx among patients in a trial related to Alzheimer's disease. The article reported that during a follow-up of patients for a median duration of approximately 29 weeks in the Vioxx group and 20 weeks in the placebo group there were l7 deaths in the Vioxx group and compared to only 5 in the placebo group. Twelve of those deaths (ll in the Vioxx group and l in the placebo group) occurred more than 48 weeks after treatment discontinuation. There were 5 fatal myocardial infarctions and 2 fatal cardiac arrests in the Vioxx group versus none in placebo for either of these adverse events. The authors did not provide a statistical analysis of the data, but they are clearly a cause for concern that the effects of Vioxx on the cardiovascular system may continue long after discontinuation of drug exposure.

146. Throughout the period described in this Complaint, Merck acted to conceal material facts regarding the risks, dangers, defects, and disadvantages of Vioxx from the general public, the medical and healthcare community, the class members, and their doctors. Merck actively and intentionally concealed this information to prevent patients and doctors from acquiring the material information necessary to conduct a fully

informed, reasonable assessment of Vioxx risks, dangers, and disadvantages, and the concealment of such information caused and resulted in the purchase of Vioxx by the class members and their consequent economic losses, damages, and harms.

147. Throughout the period described in this Complaint, Merck knowingly and intentionally failed to disclose important and material information regarding the risks, dangers, defects, and disadvantages of Vioxx to the general public, the medical and healthcare community, the class members and their doctors, while actively and affirmatively touting the benefits and advantages of Vioxx. This intentionally incomplete and materially misleading dissemination of information violated Merck's duty to fully and meaningfully communicate all material facts known to it regarding the risks, dangers, defects, and disadvantages of Vioxx, which duty Merck possessed by virtue of its superior knowledge, as described above, its relationship of trust and confidence with the class members and their doctors, and Merck's knowing and intentional decision to communicate some, but not all, of the important material information it possessed regarding Vioxx.

148. Throughout the period described in this Complaint, Merck repeatedly engaged in intentional misconduct characterized by trickery, deceit and a wanton, willful, conscious and reckless disregard of the health, rights and interests of the plaintiffs, and, in so conducting itself, acted with oppression, fraud and malice toward the class. As a result of Merck's indifference to the reckless disregard of the health and safety of Vioxx patients, they suffered both physical and economic harm, and all end-payors incurred economic damages.

CLASS ACTION ALLEGATIONS

149. Pursuant to Federal Rule Civil Procedure 23, class representative plaintiffs on behalf of themselves and all others similarly situated, seeks a nationwide class defined as follows:

> All persons residing in the United States who were prescribed and ingested Vioxx, also known as Rofocoxib in any dose during the period from May 20, l999 through September 30, 2004 (the "Class Period"), when Vioxx was withdrawn from the market, and who claim personal injuries or assert wrongful death claims arising from ingestion of Vioxx. Excluded from the class is the defendant including any parent, subsidiary, affiliate or controlled person of the defendant and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons.

Plaintiffs seek a national class through the unitary application of the New Jersey law.

New Jersey law provides for a broad remedy and as long as no out-of-state plaintiff gets less protection under its states' laws and Merck is subject to New Jersey law, there should be no objection to the unitary application of New Jersey law.

150. Alternatively, pursuant to Federal Rule Civil Procedure 23, the class representative plaintiffs for their particular state class on behalf of themselves and all other similarly situated, seek certification of the classes defined as follows:

> NEW YORK: All residents of New York who took Vioxx in any dose at any time between M ay 20, l999, when Vioxx was first approved by the United States Food and Drug Administration ("FDA") and September 30, 2004, when Vioxx was withdrawn from the market, and who claim personal injuries or assert wrongful death claims arising from ingestion of Vioxx. Excluded from the class is the defendant, including any parent, subsidiary, affiliate or controlled person of the defendant and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons.

151. Vioxx was widely prescribed and has been ingested by approximately 20 million persons. The members of the Class are so numerous that joinder is impracticable and wold involve thousands of individual actions.

152. Each class representative plaintiff is a member of the Class he/she seeks to represent.

153. In this action, key significant common issues of law and fact exist which relate to the defectiveness of Vioxx; to Defendant's knowledge, conduct and duty in its formulation, research and development, manufacturing, testing, promotion, marketing, advertising and sales; and, these common issues predominate over any issues affecting only individual Class members. Common issues of law and fact include, but are not limited to:

1. Whether Vioxx was and is unsafe for human ingestion;

2. Whether defendant designed, manufactured and/or marketed Vioxx with knowledge that it was a dangerously defective product;

3. Whether defendant acted knowingly, recklessly, or negligently in marketing and selling Vioxx;

4. Whether defendant conducted, either directly or indirectly, adequate testing of Vioxx;

5. Whether defendant acted to conceal or failed to adequately warn consumers of the adverse health hazards caused by using Vioxx;

6. Whether defendant falsely and fraudulently misrepresented in their advertisements, promotional materials and other materials, among other things, the safety of using Vioxx;

7. Whether defendant knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Vioxx from governmental regulators, the medical community and/or the consuming public;

8. Whether defendant's post-marketing safety and surveillance system exists, and if so, was designed and implemented in a reasonable manner;

9. Whether defendant designed and manufactured a drug that was dangerously defective because its use leads to or poses a substantial increased risk of the existence of potentially dangerous side effects, including, but not limited to, heart attack and stroke;

10. Whether defendant knew or should have known that the ingestion of Vioxx leads to or poses a substantial increased risk of the side effects;

ll. Whether defendant continued to manufacture, label, license, market, distribute, promote and/or sell the drug, Vioxx, notwithstanding its knowledge of the drug's dangerous nature and side effects;

l2. Whether the warnings and information defendant provided with Vioxx were adequate in warning of the potential hazards resulting from its use;

l3. Whether ingestion of Vioxx causes an increased risk of side effects;

l4. Whether there exist monitoring and testing procedures that will permit the early detection and treatment of the side effects caused by the ingestion of Vioxx;

15. Whether the increased risk of side effects from the ingestion of Vioxx warrants periodic diagnostic and medical examinations, medical research, and communications to the Class;

l6. Whether medical monitoring of plaintiff and the proposed Class who used Vioxx is reasonably necessary; and

l7. For the nationwide class, whether the unitary application of New Jersey or Pennsylvania law is appropriate.

l8. Whether the degree of reprehensibility of Merck's conduct warrants the imposition of punitive damages under controlling authority;

CLAIMS FOR RELIEF
COUNT I
NEGLIGENCE

154. Plaintiffs incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

155. Defendant is the designer, manufacturer and seller of the drug, Vioxx.

156. When placed in the stream of commerce in l999, Vioxx was not accompanied by adequate warnings regarding the significant cardiovascular risks associated with the ingestion of Vioxx. The warnings given by the defendant did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope, or severity of such injuries.

157. Defendant failed to perform adequate testing concerning the safety of the drug Vioxx in that adequate testing would have shown that Vioxx poses serious risk of cardiovascular problems which would have permitted adequate and appropriate warnings to have been given by

Defendant to prescribing physicians and the consuming public.

158. Defendant had a duty to exercise reasonable care in the design, manufacture, sale, and distribution of the dug Vioxx, including a duty to assure that the product did not cause users to suffer from unreasonable dangerous side effects when used along or in foreseeable combination with other drugs.

159. Defendant was negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, and sale of Vioxx in that, among other things, Merck:

(a) failed to use reasonable care to design an arthritis drug (Vioxx) that was safe for its intended and foreseeable uses, not defective and not unreasonably dangerous;
(b) failed to use reasonable care in designing and manufacturing Vioxx so as to make it safe for its intended uses, not defective, and not unreasonably dangerous;
(c)failed to use reasonable care to adequately warn foreseeable users such as plaintiffs of the dangers of using Vioxx, including, but not limited to adverse cardiac events;
(d) failed to use reasonable care to make reasonable tests, inspections, drug trials, and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with Defendant’s Vioxx;

(e) failed to comply with and/or to use reasonable care to comply with standards of case including accepted industry standards, FDA recommendations, government regulations, statutes, in the design, manufacture aff ixing of warnings, and otherwise production and distribution of defendant's Vioxx;
(f) failed to use reasonable care to timely remove and/or recall from the market, retrofit, and/or otherwise prevent the continued contact of plaintiffs or persons like plaintiffs with such defects and unreasonably dangerous conditions of Vioxx;
(g) failed to use reasonable care to investigate and/or use known and/or knowable reasonable alternative designs, manufacturing processes, and/or materials for Vioxx;
(h) failed to use reasonable care to warn plaintiffs of dangers known and/or reasonably suspected to Defendants to be associated with Vioxx;
(I) failed to use reasonable care to make Vioxx safe;
(j) failed to timely use reasonable care to discover the dangerous conditions or character of defendant's Vioxx;
(k) failed to use due care in the design, testing and manufacturing of Vioxx so as to prevent the aforementioned risks, including myocardial infarction and stroke, to individuals when Vioxx was used as a medication for arthritis and other pain;
(l) failed to issue proper warnings regarding all possible adverse side effects associated with the use of Vioxx and the comparative severity and duration of such adverse effects, despite the fact that the defendant knew, or should have known that numerous case reports, adverse event reports, and other data that associated Vioxx with myocardial infarction and stroke;
(m) failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Vioxx;
(n) failed to provide adequate training and information to medical care providers for the appropriate use of Vioxx;
(o) failed to warn plaintiffs and healthcare providers, prior to actively encouraging and promoting the sale of Vioxx, either directly, or indirectly, orally, in writing, or other media about the following:

1. The adverse side effects associated with the use of Vioxx, including but not limited to death, myocardial infarction and stroke; and
2. The possibility of becoming disabled as a result of using Vioxx; and

(p) failed to timely develop and implement a safer, alternative design of Vioxx, which would meet the same need without the known risks associated with Vioxx and which would not have made the product too expensive to maintain its utility.

160. Despite the fact that the Defendant knew or should have known that Vioxx caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, the Defendant continued to market Vioxx to consumers, including plaintiff(s) and the Class, when there were safer alternative methods of reducing arthritis.

161. Defendant knew or should have known that consumers such as Plaintiff(s) and the Class would forseeably suffer injury as a result of the Defendant's failure to exercise ordinary care as described above.

162. As the direct and proximate cause and legal result of the Defendant's failure to supply appropriate warnings for the drug, Vioxx, and as a direct and legal result of the negligence, carelessness, other wrongdoing and actions of Defendant described herein, the Vioxx recipient plaintiff and the class ingested Vioxx and suffered significant injury.

163. Defendant's negligence was a proximate cause of the harm suffered by the Vioxx recipient plaintiff and the Class as previously set forth herein.

164. As a direct and proximate cause and legal result of the Defendant's negligence, carelessness, and other wrongdoing and actions of the Defendant as described herein, the Derivative Claimants and class member Derivative claimants have suffered a loss of consortium, services, love and affection, and have incurred financial expenses and have suffered economic losses.

COUNT II
STRICT PRODUCT LIABILITY

(Failure to Warn)

165. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

166. The Vioxx manufactured and/or supplied by Defendant was and is unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendant failed to perform adequate testing in that adequate testing would have shown that Vioxx possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made with respect to the use of Vioxx. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

167. The Vioxx manufactured and/or distributed and/or supplied by Defendant was defective due to inadequate post-marketing warning or instruction because Defendant failed to provide adequate warnings to users or consumers of Vioxx and continued to aggressively promote Vioxx.

168. As the proximate cause and legal result of the defective condition of Vioxx as manufactured and/or supplied and/or distributed by Defendant, and as a direct and legal result of the conduct of Defendant described herein, plaintiffs and class members have been damaged.

COUNT III

STRICT PRODUCT LIABILITY

(Pursuant to Restatement Second of Torts 402a (l965))

169. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

170. The Vioxx manufactured and/or distributed and/or supplied by Defendant was defective in design or formulation in that, wen it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeds the benefits associated with the design or formulation of the drug.

171. Alternatively, the Vioxx manufactured and/or distributed and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of arthritis.

172. There existed, at all times material hereto, safer alternative medications.

173. Defendant did not perform adequate testing on Vioxx. Adequate testing would have shown that Vioxx caused serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

174. The Vioxx manufactured, designed, marketed, distributed and/or sold by defendant was unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of Vioxx, and the severity and duration of such adverse effects; the warning given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

175. Defendant did not warn the FDA of material facts regarding the safety and efficacy of Vioxx, which facts defendant knew or should have known.

176. The Vioxx manufactured and/or distributed and/or supplied by Defendant was defective due to inadequate post-marketing warning or instruction because, after the Defendant knew or should have known of the risk of injury from Vioxx, they failed to provide adequate warnings to users or consumers of Vioxx and continued to promote Vioxx.

177. As a result of the defective condition of Vioxx, plaintiffs and class members have been damaged.

COUNT IV

NEW JERSEY CONSUMER FRAUD ACT (N.J.S.A. 56:8-2 et seq.)

178. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

179. Prescription drugs such as Vioxx are “merchandise”, as that term is defined by the New Jersey Consumer Fraud Act (“Act”) N.J.S.A. 56:8-l et seq.

180. Defendant is the researcher, developer, designer, tester, manufacturer, formulator, packager, inspector, labeler, distributor, marketer, promoter, seller and/or otherwise released Vioxx into the stream of commerce.

181. Defendant knew or should have known that the use of Vioxx causes serious and life threatening injuries but failed to warn the public, including Plaintiffs of same.

182. In violation of the Act, defendant made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from

Plaintiffs in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Vioxx. Moreover, defendants downplayed and/or understated the serious nature of the risks associated with Vioxx in order to increase the sales of Vioxx and secure a greater share of the COX-2 market, and made efforts to control medical opinion by intimidation and by funding misleading literature and professional presentations.

183. Defendant's statements and omissions were undertaken with the intent that the FDA, Canadian regulators, physicians, and consumers, including the plaintiffs would rely on the defendant's statements and/or omissions.

184. Defendant knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Vioxx but remained silent because defendant's appetite for significant future profits far outweighed their concern (if any) for the health and safety of the plaintiffs.

185. Plaintiffs' physicians prescribed and/or otherwise provided plaintiffs with Vioxx, and plaintiffs consumed Vioxx, primarily for personal and family reasons and suffered and will suffer ascertainable losses of money as a result of the defendant's use or employment of the methods, acts, or practices alleged herein.

186. The aforesaid promotion and release of Vioxx into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression

or omission in connection with the sale or advertisement of such merchandise or services by defendant, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-l et seq.

187. Defendant concealed, omitted or minimized the side effects of Vioxx or provided misinformation about adverse reactions, risks and potential harms from Vioxx and succeeded in persuading consumers to purchase and ingest Vioxx despite the lack of safety and the risk of adverse medical reactions, including cardiovascular events and gastrointestinal effects.

188. Defendant's practice of promoting and marketing Vioxx created and reinformed a false impression as to the safety of Vioxx, thereby placing consumers at risk of serious and potential lethal effects.

189. Vioxx lacked appropriate warnings, and the packaging and labels used by defendant were misleading, inaccurate, incomplete and/or untimely.

190. Defendant violated their post-manufacture duty to warn which arose when they knew, or with reasonable care should have known, that Vioxx was injurious and sometimes fatal.

191. At the time when consumers purchased and ingested Vioxx, defendant intended that others would rely upon the concealment, suppression or omission of the risks of ingesting Vioxx.

192. Defendant's actions in connection with manufacturing, distributing, and marketing of Vioxx as set forth herein evidence a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2 et seq.

193. Defendant acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

194. As a proximate result of the acts of consumer fraud set forth above, plaintiffs have purchased an unsafe product and incurred and will incur monetary expense and economic loss and the risk to themselves and members of their household that they would, by consuming Vioxx, thereby suffer harm as previously set forth herein.

WHEREFORE, plaintiffs demand judgment against defendant for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

VIII. PRAYER FOR RELIEF

WHEREFORE, plaintiffs on behalf of themselves and the class members they seek to represent, request the following relief:

A. An order declaring this action to be proper class action of class actions pursuant to Federal Rule of Civil Procedure 23, establishing an appropriate class or classes, and finding that plaintiffs are proper representatives of the Class or Classes;

B. Awarding plaintiffs and Class members compensatory damages in an amount to be proven at trial for the wrongful acts complained of;

C. Awarding plaintiffs and Class members statutory damages as permitted, including any applicable exemplary damages;

D. Awarding plaintiffs and Class members punitive damages to deter Defendant's outrageous and wanton conduct and flagrant disregard for the lives and health of the class members;

E. Awarding plaintiffs and the Class pre-judgment and post-judgment interest;

F. Awarding plaintiffs and the Class their costs and expenses in this litigation, including, but not limited to expert fees and reasonable attorneys fees; and

G. Awarding plaintiffs and the Class such other and further relief as may be just and proper.

JURY TRIAL DEMAND

Plaintiffs demand on behalf of themselves and all others similarly situated, a trial by jury on all issues so triable.

Respectfully submitted,

DATED: January 16 2006

WEINER, CARROLL & STRAUSS
Attorneys for Plaintiffs

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